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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,337	12/07/2001	Patrick Benoit	08888.0530	9440
7590	09/18/2006			EXAMINER GIBBS, TERRA C
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P. 1300 I Street, N.W. Washington, DC 20005-3315			ART UNIT 1635	PAPER NUMBER

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/005,337	BENOIT ET AL.
	Examiner Terra C. Gibbs	Art Unit 1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### **Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 23 August 2006.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 40-56 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) 40-44, 46, 47 and 49-56 is/are allowed.

6)  Claim(s) 45 and 48 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. \_\_\_\_ .  
3)  Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_ . 5)  Notice of Informal Patent Application  
6)  Other: \_\_\_\_ .

### **DETAILED ACTION**

This Office Action is a response to Applicant's Amendment and Remarks filed August 23, 2006.

Claims 34-37 have been canceled. Claims 40, 54, and 55 have been amended.

Claims 40-56 are pending in the instant application.

Claims 40-56 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Withdrawal of Finality***

Applicants received a Final Office Action mailed June 12, 2006. After careful reconsideration of the claims, the Examiner has decided to reopen prosecution of the instant application because the Examiner did not raise a 35 U.S.C. 112 issue earlier during prosecution. A new Non-Final Office Action on the merits follows:

#### ***Claim Rejections - 35 USC § 112***

In the previous Office Action mailed June 12, 2006, claims 40-56 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. **This rejection is withdrawn** in view of Applicant's Amendment filed August 23, 2006. Specifically, the Examiner is withdrawing this rejection in view of

Applicant's Amendment to the claims to remove the language, "or a sequence having at least 93% identity to SEQ ID NO:1".

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 45 and 48 are indefinite because they recite the term, "wherein the protein of therapeutic interest" in line 2 of each claim. There is insufficient antecedent basis for this term in the claims because claim 41 from which claims 45 and 48 depends therein recites, "a protein or an RNA of therapeutic interest". Replacing the claims with the term, "wherein the protein or an RNA of therapeutic interest" would remedy the instant rejection.

***Allowable Subject Matter***

Claims 40-44, 46, 47, and 49-56 are allowable. Claims 40-44, 46, 47, and 49-56 are allowable because the prior art does not teach or fairly suggest an isolated polynucleotide comprising SEQ ID NO:1, wherein said polynucleotide comprises at least 92 nucleotides 3' to the transcription start position +1, and wherein said polynucleotide in the absence of inverted terminal repeat sequences form human adeno-associated

virus specifically induces expression in cardiac cells *in vivo* of a gene which is operably linked to said polynucleotide and a vector comprising said polynucleotide.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is 571-272-0758. The examiner can normally be reached on 9 am - 5 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

tcg  
September 8, 2006

SEAN McGARRY  
PRIMARY EXAMINER  
1635